JUL 19 2012

Attachment I 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K112622

1. Date of Submission: August 12,2011

2. Sponsor

Beijing Choice Electronic Technology Co., Ltd.
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3. Submission Correspondent

Ms. Diana Hong & Mr. Tarzan Wang
Mid-Link Consulting Co., Ltd
P.O. Box 237-023, Shanghai, 200237, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: Handheld ECG Monitor
Proposed Device Model: MD100A1-F

Classification: Class II
Product Code: DPS
Regulation Number: 21 CFR 870.2340
Review Panel: Cardiovascular

Intended Use Statement:

The Handheld ECG Monitor OTC version is intended to record and store Lead I ECG signals. and display three ECG parameters for home health care use. The intended users are adults above 20 years old. This device is not intended to substitute for a hospital diagnostic ECG device. Users with implanted pacemaker are not recommended to use this device. The Handheld ECG Monitor OTC version has simple user interface without ECG trace viewing function.

5. Predicate Device Identification

510(k) Number: K052303
Product Name: ReadMyHeart
Manufacturer: DailyCare BioMedical Inc.

6. Device Description

Handheld ECG Monitor is a handheld, personalized use and affordable ECG Lead I recording device with metal electrode that records user's cardiac function for daily health check. It takes ECG signals of users by the method of touching the metal electrode embedded on the device by palm. The device will record user's ECG signal for 30seconds, and three measured parameters including heart rate (HR), ST segment and QRS interval, are displayed on LCD of the device. It is not intend for automatic analysis or ECG signals monitor.

The device can store 200 records. Handheld ECG Monitor is powered by internal battery source. And the device has the function of system setting including date, time, ID number, backlight and Beep sound.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1: 1988 +A1:1991+A2:1995, Medical Electrical Equipment – Part 1: General requirements for safety.
IEC 60601-2-25: 1993 +A1: 1999, Medical Electrical Equipment - Part 2: Particular requirements for the safety of electrocardiographs.
IEC 60601-1-2: 2007, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility – Requirements and tests.
IEC60601-2-47: 2001, Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
AAMI/ANSI EC38: 2007, Medical electrical equipment - Part 2-47: Particular requirements for the

safety, including essential performance, of ambulatory electrocardiographic systems.
ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Substantially Equivalent Conclusion

The proposed device, Handheld ECG Monitor, is determined to be Substantially Equivalent (SE) to the predicate device, ReadMyHeart (K052303), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 19 2012

Beijing Choice Electronic Technology Co., Ltd.
c/o Diana Hong
Submission Correspondent, Mid-Link Consulting Co., Ltd
P.O. Box 237-023
Shanghai, 200237, China

Re: K112622
Trade/Device Name: Handheld ECG Monitor MD100A1-F
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: July 2, 2012
Received: July 6, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment V Indications for Use

510(k) Number: K112622

Device Name: Handheld ECG Monitor

Indications for Use:

The Handheld ECG Monitor OTC version is intended to record and store Lead I ECG signals, and display three ECG parameters for home health care use. The intended users are adults above 20 years old. This device is not intended to substitute for a hospital diagnostic ECG device. Users with implanted pacemaker are not recommended to use this device. The Handheld ECG Monitor OTC version has simple user interface without ECG trace viewing function.

☐PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☒OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112622